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MAY 20 2010

Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

Dear Ms. Axelrad:

Transmitted herewith is a copy of the application for patent term extension of U.S. Patent No. 7,323,493. The application was filed on August 20, 2009, under 35 U.S.C. § 156. Please note that Applicant has also applied for extension of U.S. Patent No. 5,223,510 (your docket no. FDA-E-2010-0039) based on the same regulatory review period, i.e., NDA No. 22-245, pursuant to the provisions of 37 C.F.R. § 1.785.

The patent claims the human drug product MULTAQ®. MULTAQ® was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. Subject to final review, the subject patent is considered to be eligible for patent term extension. Thus, a determination by your office of the applicable regulatory review period is necessary. Accordingly, notice and a copy of the application are provided pursuant to 35 U.S.C. § 156(d)(2)(A).

Inquiries regarding this communication should be directed to the undersigned at (571) 272-7755 (telephone) or (571) 273-7755 (facsimile).

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Associate Commissioner
for Patent Examination Policy

cc: John D. Conway
sanofi-aventis U.S. Inc.
U.S. Patent Operations MAILCODE: BWD -303A
Route #202-206/P.O. Box 6800
Bridgewater, NJ 08807-0800

RE: MULTAQ® (dronedarone hydrochloride)
Docket No. FDA-2010-E-0040